

### REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the following remarks. With the above amendment, claims 6, 81-83, and 86-89 have been amended for clarity and to more particularly define certain aspects of Applicants' invention. Claims 6 and 81-89 are currently pending. It should be noted that the above amendments are made without prejudice to prosecution of any or all subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application.

Applicants kindly thank the Examiner for the productive interview conducted via telephone with her and John LeGuyader on March 4, 2003 during which three primary issues were discussed. Examiners Epps and LeGuyader agreed that amending the claims from "a sequence of SEQ ID NO:474" to "the sequence of SEQ ID NO:474" would be acceptable to overcome certain aspects of the rejection under 35 U.S.C. § 112, first paragraph as discussed further below. Applicants have amended the claims accordingly, without acquiescence. With regard to % identity, the Examiners indicated that if representative species of the genus are disclosed, then Applicants are entitled to the claimed genus comprising sequences having at least 90% identity to the sequence of SEQ ID NO:474. While Applicants maintain that the disclosure of representative species is not necessary for the skilled artisan to readily recognize that Applicants' were in possession of a genus of sequences related by % identity to SEQ ID NO:474, the description of SEQ ID NO:463 as discussed further below, confirms that Applicants' were in possession of a genus of sequences related by % identity to SEQ ID NO:474. Finally, Examiner LeGuyader indicated that, barring any prior art, Applicants are entitled to an isolated polynucleotide comprising a sequence consisting of at least 20 contiguous nucleotide of the sequence provided in SEQ ID NO:474. In a subsequent conversation, Examiner Epps indicated that the appropriate search of the prior was carried out by the PTO and will be analyzed fully in due course.

### ***Claims Rejected Under 35 U.S.C. § 112***

Claims 6 and 81-89 stand rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Action alleges that the scope of the instant claims includes numerous structural variants and neither the specification or the claims provide any guidance as to what specific changes should be made. Additionally, the Action alleges that in order to determine whether or not the sequences function for the detection of breast cancer, further experimentation must be performed for each individual sequence. Therefore, the Action alleges that because further experimentation is necessary, the claimed invention was not ready for patenting at the time of filing of the instant application. The Action further contends that the phrase "a sequence of SEQ ID NO:474" reads on a sequence of SEQ ID NO:474 from one nucleotide to the entire length of SEQ ID NO:474.

Applicants respectfully traverse this rejection. Applicants disagree with the contention that they were only in possession of the specific sequence of SEQ ID NO:474 at the time this application was filed. Moreover, Applicants submit that to accept such a position would result in the exclusion of an entire class of sequences related to SEQ ID NO:474 that are useful in the context of the Applicants' invention, despite the fact that the skilled artisan would immediately recognize the value of sequences related to SEQ ID NO:474 in the context of the Applicants' disclosure.

Accordingly, Applicants believe their disclosure adequately establishes possession of the full scope of the currently claimed invention. As an initial matter, Applicants have disclosed the detailed structure of B726P, *e.g.*, SEQ ID NO:474, and have also identified B726P as a sequence having a tumor-specific expression profile. Thus, in the context of the presently claimed invention, the skilled artisan would recognize that the tumor specificity of expression of B726P represents a distinguishing identifying characteristic common among the polynucleotides of the claimed invention.

Further still, in view of this identifying characteristic, the skilled artisan would immediately recognize that the Applicants were in possession of much more than the specifically recited species of SEQ ID NO:474. In view of the tumor-specific expression profile identified by the Applicants for this sequence, the skilled artisan would undoubtedly understand and expect that a multitude of sequences structurally related to SEQ ID NO:474, *e.g.*, sequences having at least 90% identity to SEQ ID NO:474, and fragments thereof, would be diagnostically useful in

the same capacity as the specific species of SEQ ID NO:474. More particularly, sequences having at least 90% identity with SEQ ID NO:474, based upon their structural similarity to, and thus specificity for, a sequence of SEQ ID NO:474, will hybridize, using assays known in the art and described in the specification, to a sequence of SEQ ID NO:474, and accordingly would be useful in detecting over-expression of SEQ ID NO:474 in a biological sample in the same manner as one would use the precise sequence of SEQ ID NO:474 to detect overexpression of SEQ ID NO:474 in a biological sample. This understanding and expectation on the part of the skilled artisan is soundly based upon fundamental scientific principles of nucleic acid hybridization, namely that a sequence having at least 90% identity to a sequence of SEQ ID NO:474, or fragments of SEQ ID NO:474, will indeed hybridize to the sequence of SEQ ID NO:474 and therefore will be useful in detecting cancers associated with over-expression of SEQ ID NO:474, despite the fact that the sequences are not identical with SEQ ID NO:474.

Moreover, by the amendment in response to the Office Action dated May 9, 2002, Applicants specifically incorporated this illustrative identifying characteristic into the claims under consideration, such that a polynucleotide of the invention is one that is "useful in the detection of breast cancer." Accordingly, in view of the Applicants' identifying characteristic disclosed for SEQ ID NO:474, Applicants respectfully submit that the skilled artisan would appreciate that Applicants were in clear possession of a genus of sequences related by % identity to SEQ ID NO:474 that would be similarly useful in a diagnostic context based upon their specificity for the sequence of SEQ ID NO:474. Applicants respectfully submit that a requirement for further experimentation is not a factor in determining whether written description has been satisfied. The instant claims are however fully enabled by the specification as filed and any experimentation that might be required by the skilled artisan to make and use the instant invention would be routine and therefore not undue.

Moreover, Applicants submit that the specification discloses splice variants of B726P, for example on page 122, lines 5-18. The polynucleotide of SEQ ID NO:463 is 95.2% identical to the polynucleotide of SEQ ID NO:474 (see the attached alignment, generated using DNASTAR, a standard sequence analysis program known in the art and described on page 30, lines 7-20 of the specification as filed). Therefore, while Applicants maintain that the disclosure of SEQ ID NO:463 is not necessary for the skilled artisan to readily recognize that Applicants'

were in possession of a genus of sequences related by % identity to SEQ ID NO:474, the description of SEQ ID NO:463 further confirms that Applicants' were in possession of a genus of sequences related by % identity to SEQ ID NO:474.

Applicants further submit that the claims as amended recite "the sequence of SEQ ID NO:474" therefore obviating the rejection regarding "a sequence of SEQ ID NO:474".

In view of the above remarks, Applicants submit that the instant claims fully comply with the written description requirements of 35 U.S.C. § 112, first paragraph. Reconsideration of the Examiner's rejection is respectfully requested.

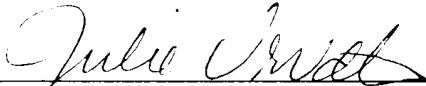
The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all of the claims remaining in the application are now allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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